



The Vitamin Marketing Experts

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March 10, 1998

Dr. Elizabeth Yetley  
Director of the Office of Special Nutritionals  
Division of Programs and Enforcement Policy  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street HFS-455  
Washington, D.C. 20204

Dear Dr. Yetley:

Notice is hereby given pursuant to the requirements of Section 403(r)(6)(21 U.S.C. 343(r)(6) of the Federal Food, Drug and Cosmetic Act of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING HAWTHORNE. FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING HAWTHORNE was first marketed with these statements of nutritional support on Friday, March 6, 1998. The statements of nutritional support are as follows:

"*Hawthorne* has been shown to strengthen the heart muscles and to contain anti-inflammatory properties. It is a valuable addition to any man's daily nutritional program as he ages".

"*Hawthorne* has a history of long term use in helping to strengthen the heart muscles. In addition, its anti-inflammatory properties are especially beneficial to mature adults".

"*Hawthorne* the leading herb for heart health in Europe. Is also an anti-inflammatory".

"*Hawthorne* for healthy heart function"

*Hawthorne* (latin name: *crataegus laevigata*), is a small, shrub-like tree commonly found in Europe, Western Asia and North Africa. In Europe, where *Hawthorne* is widely used as a heart tonic, standardized extracts of the herb are made from the leaves and flowers.

Vitexin, which is a flavonoid found in concentrated amounts in the leaves and flowers, has been determined through scientific research to be one of the active ingredients responsible for *Hawthorne*'s ability to increase heart muscle efficiency and strength. Family Essentials™ Today's Man™ contains *Hawthorne* that is standardized to have the vitexin content used in studies. Several of these studies show that *Hawthorne* extracts help patients increase their exercise tolerance through overall improved heart function.

Very truly yours,  
MASON VITAMINS, INC.

Sonia C. Rodriguez  
VP Marketing & Regulatory Affairs

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### **STUDIES FOR HAWTHORNE CLAIMS**

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